

REMARKS

Claims 27-29, 33, 34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59, and 65 are under examination in this case.¹ All claims stand rejected under 35 U.S.C. § 112, first and second paragraphs. In addition, claims 27-29, 34, 36, 38-43, 45, and 47 stand rejected under 35 U.S.C. § 102(e), and claims 37, 47, 49, 51, 53, 55, 57, and 59 stand rejected under 35 U.S.C. § 103. Each of these issues is addressed below.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 27-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59, and 65 stand rejected under 35 U.S.C. § 112, second paragraph. The Office states (at page 5):

Claim 27 recites “said method comprising providing AAV particles having a structural protein of adeno-associated virus that comprises at least one mutation in the VP3 located before and/or after at least one amino acid in the sequence”. The claim interpretation is broad and reads on any mutation, including a mutation before or after said sequences. The claim language does not clearly define the metes and bounds of the claim[ed] invention.

As an initial matter, Applicants point out that the fact that a claim is “broad” does not render it indefinite. Nonetheless, in view of Applicants’ amendments, this rejection may be withdrawn. The current claims do not read “on any mutation.” They have been clarified to recite insertions positioned in the AAV capsid protein at or directly adjacent to one of seven specific amino acid locations, SEQ ID NOS: 2-9. This rejection may be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 27-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59, and 65 stand further rejected under 35 U.S.C. § 112, first paragraph. As applied to the current claims, this rejection is respectfully traversed.

¹ Applicants note that the Office Action, at page 2, inadvertently omits claim 55 in the listing of examined claims.

Claims 36 and 47 remain rejected as lacking an enabling disclosure. The Office states (at page 3):

The claims encompass any and all mutations in the VP3 either before or after any one of the amino acids recited in any of SEQ ID NO's 2-7. Therefore, given the broadest reasonable interpretation of the claims, the claims encompass any mutation (insertion, deletion, or substitution) anywhere in the VP3 protein before or after any amino acid, as long as it is one of the amino acids which appears in one of the recited sequences.

This rejection may be withdrawn. As indicated above, Applicants' claims are now limited to insertions made at one of seven particular locations and do not "encompass any and all mutations" in the VP3 sequence.

In addition, claims 27-29, 33-34, 36-43, 45, 47, 49, 51, 53, 55, 57, 59, and 65 were newly rejected as lacking a written description. This rejection turns on the assertion that:

There are a limited number of species of the claimed genus disclosed that are within the scope of the claimed genus, i.e., amino acid sequences SEQ ID NO: 2, 3, 4, 5, 6, and 7, 8, and 9. The disclosure of even a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described, namely species drawn to mutations (including insertions, deletions, and substitutions) anywhere before and/or after any amino acid in the specified sequences. Thus, there is substantial variability among the species. In the absence of sufficient recitation of distinguishing characteristics of the genus, the specification does not provide adequate written description of the claimed genus. Office Action, page 7.

As above, the Examiner is directed to Applicants' clarifying amendment to claim 27. Independent claim 27 now specifies that the mutations are insertions and that the insertions occur in or directly adjacent to one of SEQ ID NOS: 2, 3, 4, 5, 6 and 7, 8, or 9. The written description rejection should be withdrawn.

Rejection under 35 U.S.C. § 102(e)

Claims 27-29, 30, 34, 36, 38-43, 45, and 47 also stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,491,907. This rejection is based on the assertion that:

The [claimed] mutation doesn't have to be anywhere in the recited sequences themselves, but rather can be in any amino acid anywhere C or N terminally to any of the amino acids in any of the recited sequences. Therefore the art anticipates the claimed invention. Office Action, pages 3-4.

As applied to the currently amended claims, this rejection may be withdrawn. By the present amendment, Applicants have clarified that the claimed mutations are insertions that, rather than being "anywhere in the recited sequences," are instead positioned in or directly adjacent to one of the seven specified AAV capsid locations. None of these insertion locations is disclosed in the '907 reference, and this rejection may be withdrawn.

Rejections under 35 U.S.C. § 103

Claim 37 stands rejected, under 35 U.S.C. § 103, as being unpatentable over U.S. Patent 5,276,136, and claims 37, 47, 49, 51, 53, 55, 57, and 59 stand rejected, under 35 U.S.C. § 103, as being unpatentable over U.S. Patent 6,491,907 in view of Spear or Yang. These rejections are respectfully traversed.

With respect to claim 37, it is noted that U.S. Patent 5,276,136 fails to disclose anything about AAV. It cannot therefore suggest the claimed AAV purification technique based on altered chromatographic properties resulting from the insertion of SEQ ID NO: 1 into one of the particular AAV capsid sites listed in independent claim 27. This basis for the rejection should be withdrawn.

Further, the rejection of claims 37, 47, 49, 51, 53, 55, 57, and 59 over U.S. Patent 6,491,907 in view of Spear or Yang is based on the assertion that the previous claims covered mutations located anywhere in the AAV capsid sequence. In view of Applicants'

clarifying amendment, this rejection may be withdrawn. As amended, independent claim 27 (from which the rejected claims depend) now specifies that the mutations are insertions located in or directly adjacent to one of seven specified capsid locations. The '907 patent does not disclose or suggest the specific insertion sites recited in claim 27, nor do Spear or Yang. This rejection may also be withdrawn.

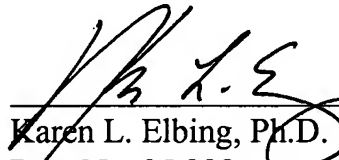
CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is respectfully requested.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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